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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,974	08/09/2000	Thomas Teufel	381-86	5643

7590 09/21/2005

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/635,974	TEUFEL, THOMAS	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *July 5th, 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *2 and 6-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12.27.2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on July 5th, 2005 is acknowledged. Claims 1, 3-5 and 46-48 are pending and examined on the merits.

2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Response to Arguments

3. The response filed on July 5th, 2005 including amendments to claim 1 has been acknowledged.

4. The rejection of claims 1, 3-5 and 46-48 under 35 USC 112, first paragraph is maintained.

The response filed on July 5th, 2005 has been carefully considered but is deemed not to be persuasive. The response states that "the specification discloses treatment of a hyperproliferative disease with an EGFR antibody or other EGFR antagonist (e.g., page 3, lines 10-15) and provides that the EGFR antagonists of the invention inhibit excess growth of cells associated with the hypreproliferative disease when administered in an effective amount (page 5 lines 12-17, in particular) and also that the specification provides dosage guidelines and amounts." In response to this argument, this is merely a contemplation of the treatment of the hyperproliferative disease with an EGFR antibody or other EGFR antagonist, and the data presented in the examples of the instant application does not convince one skilled in the art that the applicant is enabled for the scope of the invention as claimed. As stated by the examiner in the office action

mailed on 01/03/2005, the specification confines its teachings to methods comprising the administration to a cancer patient, who happened to also suffer form psoriasis, of a specific of a specific chimeric version of the murine 225 antibody anti-EGFR antibody in combination with a chemotherapeutic agent with is designated at "CPT-11(cisplatin)". However, CPT-11 is not the same as cisplatin. CPT-11 is also known as irinotecan hydrochloride (an alkaloid extract from plants; see PDR entry for CAMPTOSAR, irinotecan hydrochloride) is a different chemical compound from cisplatin, which has the chemical name of cis-diamminedichloro-platinum II, and is a platinum salt. Because the specification teaches that a human cancer patient was administered in combination of the antibody C225 and a chemotherapeutic agent that was wither CPT-11 or cisplatin, it is not clear whether the psoriasis was improved because of the C225 administration, the chemotherapeutic agent (CPT-11 or cisplatin) administration, of the combination of two. In contrast to the working examples provided by the specification and the argument presented by the applicant "the applicant discovered that the improvement in psoriasis was .....use the anti-EGFR/HER1 antibody alone (pages 5-6 of the response)", the scope of claims is broadly drawn to the treatment of psoriasis with an EGFR antibody and does not commensurate in scope of what the applicant is discussing.

Disclosure of treatment of a human with psoriasis, comprising systemically administering to said human an amount of an EGFR/HER1 antibody in combination with a chemotherapeutic agent is insufficient support for claims which are broadly drawn to a method of treating psoriasis using the antibody alone. The applicant states that "even though the examples describe co administration of an anti-EGFR/HER1 antibody with a

therapeutic agent, the specification clearly sets forth how to use the anti-EGFR/HER1 antibody alone" (page 5 last paragraph). This argument is deemed not to be persuasive because it is the applicants' responsibility to provide the office with enough evidence to support and that is commensurate within the scope of the claimed invention. The courts have held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based In some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not In compliance with the first paragraph of U.S.C. 1 129 that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill In the art; In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement In the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific taw; In cases involving unpredictable factors, such as chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." In re Fisher 427 F.2d 833, 166 USPQ 18 (CCPA 1970).

Therefore in light of the breadth of the claims, the lack of guidance and working examples in the art, the unpredictable nature of the art of cancer treatment, one of skill

in art would not be enabled to practice the full scope of the invention and the rejection is maintained.

5. The rejection of claim 48 under 35 USC 112, first paragraph is maintained.

The response filed on July 5th, 2005 has been carefully considered but is deemed not to be persuasive. The response states that "a deposit is not necessary even though Mab C225 is required to practice the claimed method because Mab C225 is known in the art and any required information or biological materials can routinely be obtained from publicly available material. The specification discloses that C225 is a chimerized version of Mab225 and C225 is otherwise known in the art.

In response to this argument, while the monoclonal antibody, 225, is publicly available, and the specification indicates that the chimerized 225 antibody can be synthesized from the methods provided in Wels et al (IDS – 12/27/2004), neither the reference provided nor the specification fails to describe how to make species of chimerized 225 antibody, C224 that is referred to in claim 48. As stated in the previous office action, the specification fails to provide enough information for one of ordinary skill in the art to produce a chimeric antibody with exactly the same characteristics as the C225 antibody, because the specification fails to provide the structure and specific sequence for the claimed C225 antibody. The specification provides the complementary determining regions for the antibody 225 which are same for C225. However, it is well known in the art, that the amino acid sequence of the framework regions and regions other than the CDR portion can affect the structural conformation of

an antibody and determine its antigen binding properties. Thus, because it does not appear that the C225 antibody is publicly available, and because the specification does not provide the structure of the C225 chimeric antibody, one of ordinary skill in the art cannot be assured of the ability to practice the claimed invention that requires the use of the specific species of chimerized 225 antibody, C225.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi Ph.D.
(571) 272-8789

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER